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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,414	09/25/2001	Fumiyasu Hirai	12218/1	6930

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/961,414	HIRAI ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 November 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☒ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *4,6 and 7*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *see Advisory Attachment.*

Advisory Action Attachment

1. Applicants response filed November 27, 2002 is acknowledged.

2. Applicant's submittal of Exhibit A is acknowledged. However, a full translation is required in order for the Exhibit to be considered.

Rejection Maintained

3. The rejection under 35 U.S.C. 102 (a) as being anticipated by Hirai et al in view is maintained for claims 4 and 6-7 the reasons set forth on pages 2-3, paragraph 4 of the previous Office Action.

The rejection was on the grounds that Hirai et al teach a method for removing enterotoxin which comprises bringing a body fluid containing an enterotoxin into contact with the adsorbent. Hirai et al teach that the adsorbent comprises a compound which has a log P value of at least 2.50 wherein P is a partition coefficient in an octanol-water system and which is immobilized on a water-insoluble carrier (see the Abstract). Hirai et al teach that the water-insoluble carrier is a water-insoluble porous carrier which has an exclusion limit for globular protein of from 1 $x10^4$ to 60 x 10^4 (see page 2). The method of Hirai, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that anticipation under 35 U.S.C. 102 the reference must teach each and every aspect of the claimed invention either explicitly or implied. Applicant urges that Hirai et al do no teach any methods for adsorptive removal of an enterotoxin in a body fluid. Applicant urges that TSST-1 is not an enterotoxin and the TSST-1 is a

different size (i.e. 22 kDa) than enterotoxins which are about 26 to about 28kDa. Applicant urges that TSST-1 and enterotoxins differ structurally. Applicant urges due to the difference in size and structure the skilled artisan would not consider TSST-1 to be an enterotoxin. Applicant urges that the 96% agreement in PCR results for detecting Staphylococcal enterotoxin D and TSST-1 teaches nothing about physical similarity between TSST-1 and enterotoxin D or any other enterotoxin. Applicant urges that since enterotoxin and TSST-1 are both classified as superantigens has nothing to do with structural similarity.

Applicant's arguments filed November 27, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing of the record to show why the prior art reference does not anticipate the claimed invention. The Examiner disagrees with Applicant assertion that TSST-1 has a molecular weight of about 22 kDa, Hirai et al teach that TSST-1 has a molecular weight of about 20-30kDa (page 2). While TSST-1 is not an enterotoxin, it should be noted that prior art of record has established that TSST-1 and entertoxins both have the same molecular weight, are both classified as superantigens and have 96% agreement in PCR results (see McLauhlin et al, 2000, Schlievert et al, 1993 and Mehrotra et al, 2000). Applicant's specification refers to the Hirai et al reference when it discloses that the reference teaches an adsorbent for TSST-1 comprising a compound having a log P value of not less than 2.50 as immobilized (page 2). Applicant's claimed invention relies on adsorbancy affinity with respect to a water-insoluble carrier, the specification states that "the protein to be adsorbed by the adsorbent of the invention has a molecular weight of

about 25 kDa to about 30 kDa" (page 10), TSST-1 has a molecular weight range from 20-30 kDa. The claimed invention appears to be based on the molecular weight of the protein to be removed rather than the structure of the protein to be removed. Applicant has provided no side-by-side comparison to show that the method of the prior art differs from that of the claimed method. The skilled artisan could reasonably conclude that the method to remove enterotoxin from body fluids can be used to remove TSST-1 since enterotoxins and TSST-1 have similar characteristics. There is no reason why the invention of the prior art would not anticipate the claimed invention.

4. No claims allowed.

5. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
January 15, 2003

NITA MINNIFIELD
PRIMARY EXAMINER
1/7/03